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Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

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FRATERNAL ORDER OF POLICE, FORT LAUDERDALE LODGE 31, INSURANCE TRUST FUND, on behalf of itself and all others similarly situated,	:
Plaintiff,	: Civ. Action No. _____
v.	: CLASS ACTION COMPLAINT : AND JURY DEMAND
UNIMED PHARMACEUTICALS, INC.; SOLVAY PHARMACEUTICALS, INC.; WATSON PHARMACEUTICALS, INC.; PAR PHARMACEUTICALS, INC.; and PADDOCK LABORATORIES, INC.,	:
Defendants.	:

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Plaintiff, Fraternal Order of Police, Fort Lauderdale Lodge 31, Insurance Trust Fund (“Plaintiff” or “FOP Trust”), on behalf of itself and all others similarly situated, files this Class Action Complaint against Defendants, Unimed Pharmaceuticals, Inc. (“Unimed Pharmaceuticals”), Solvay Pharmaceuticals, Inc. (“Solvay”) (collectively, with Unimed

Pharmaceuticals; “Unimed”), Watson Pharmaceuticals, Inc. (“Watson”), Par Pharmaceuticals, Inc. (“Par”), and Paddock Laboratories, Inc. (“Paddock”) (collectively, “Defendants”). Plaintiff, upon knowledge as to matters relating to itself and upon information and belief as to all other matters, alleges as follows:

**NATURE OF THE ACTION**

1. This antitrust action seeks damages resulting from Defendants’ unlawful delay and exclusion of a generic version of the drug sold under the brand name Androgel, a topical testosterone, a drug marketed by Unimed as a testosterone replacement therapy (“TRT”) for males with a deficiency or absence of endogenous testosterone.

2. Defendants substantially delayed the onset of generic competition of testosterone topical by orchestrating a conspiracy to restrain trade, and monopolize the U.S. market for Androgel and its generic equivalents. Among other things, Unimed entered into illegal agreements with its prospective generic competitors Watson, Par and Paddock (collectively the “Generic Defendants”) whereby in late 2006 Unimed agreed to pay the Generic Defendants significant sums of money, as well as other forms of compensation in exchange for the Generic Defendants agreeing not to sell their generic versions of Androgel until 2015 in the case of Watson, the first Abbreviated New Drug Application (“ANDA”) filer, and until 2016 for the other Generic Defendants.

3. Defendants realized that the underlying patent, United States Patent No. 6,503,894 (the “894 patent”), listed by Unimed in the U.S. Food & Drug Association’s “Orange Book” as covering Androgel, was susceptible to attack as being invalid or unenforceable. After Watson and Paddock filed ANDAs, Unimed sued them for patent infringement. The Generic

Defendants alleged that their generic versions of testosterone topical did not infringe on the 894 patent and claimed that the patent was invalid because Unimed withheld important information from the Patent and Trademark Office (“PTO”). However, prior to the expiration of the 894 patent, the Defendants entered into agreements to share in Unimed’s monopoly profits, settle their patent challenges and not compete by selling low-cost generic versions for a period of nine years.

4. Brand name drugs and their generic versions contain the same active ingredient(s), and generics are recognized by the Food and Drug Administration (“FDA”) to be just as safe and effective as their brand drug counterparts. The only material difference between generics and brand name drugs is the price. Generics are usually at least 30% less expensive than their brand counterparts when there is one generic competitor. The discount usually increases to 50-80% (or higher) when multiple generic competitors exist in the market. In fact, AB-rated generic versions of brand name drugs typically take 80% or more of the sales of the brand name drugs within the first year of the entry of the generic drug into a given market.

5. Defendants’ Agreements (to share in Unimed’s monopoly profits, settle their patent challenges and not compete by selling low-cost generic versions) are anticompetitive as Defendants apportioned among them the surplus in monies from the earlier generic entry of Androgel, that should have accrued to purchasers, and therefore has denied Plaintiff and other indirect purchasers of Androgel the benefits of competition and of less expensive, generic versions of Androgel. As a result, Plaintiff and members of the Class, defined below, have paid supracompetitive prices for Androgel.

### **JURISDICTION AND VENUE**

6. This action is brought under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive relief, and the costs of suit, including reasonable attorneys' fees, for injuries to Plaintiff and members of the class resulting from, *inter alia*, Defendants' violations of the federal antitrust laws.

7. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 22 and 26, 28 U.S.C. §§ 1331, 1337(a). The Court also has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d)(2), because the matter in controversy, upon information and belief, exceeds \$5,000,000, exclusive of interest and costs, and this matter is a class action in which Class members are citizens of states other than Defendants. This court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1337(a).

8. Venue is proper in this District under 15 U.S.C. §§ 15, 22, and 26, and under 28 U.S.C. § 1391, because (1) Defendants transact business and are found within this District; (2) one of the Defendants' principal place of business is in this district; and (3) a substantial portion of the affected trade and commerce described herein has been carried out in this District.

### **PARTIES**

9. Plaintiff, The Fraternal Order of Police, Fort Lauderdale Lodge 31, Health Trust ("FOP Trust" or "Plaintiff") is a governmental health insurance plan established pursuant to Florida law and resolution of the Fort Lauderdale City Commission. The FOP Trust is managed by a Board of Trustees and provides health and major medical insurance, including prescription drugs, to active and retired Ft. Lauderdale City police officers and their dependents. At all times relevant to this action, Plaintiff is and has been a citizen and resident of Florida.

10. During the Class Period (described below), Plaintiff, in its capacity as a third-party payor paid supracompetitive prices for Androgel, which was prescribed to one or more of its participants or beneficiaries, and has thereby been injured as a result of Defendants' unlawful conduct.

11. Defendant, Solvay, is a Georgia corporation with its principal place of business in Marietta, Georgia, and is a citizen of Georgia. Solvay is the U.S. subsidiary of Solvay Pharmaceuticals. Together with its wholly owned subsidiary, Unimed Pharmaceuticals, Solvay develops, manufactures, and markets pharmaceuticals and related products, including Androgel, in the United States. Solvay negotiated and/or approved Unimed Pharmaceuticals' relevant anticompetitive agreements concerning Androgel, the filing and prosecution of the patent case against Par, Paddock and Watson, and has a significant financial interest in Androgel.

12. Defendant, Unimed Pharmaceuticals, is a wholly owned subsidiary of Solvay, with its principal place of business in Marietta, Georgia, and is a citizen of Georgia. Unimed Pharmaceuticals develops, manufactures, and markets pharmaceuticals and related products, including Androgel, in the United States. Unimed Pharmaceuticals focuses on developing and marketing drugs in the therapeutic areas of cardiology, men's health (urology and endocrinology) and certain infectious diseases.

13. Defendant, Watson is a Nevada corporation with its principal place of business in Corona, California, and is a citizen of California and Nevada. Watson principally develops, manufactures and markets generic versions of brand name drugs.

14. Defendant, Par, is a Delaware corporation with its principal place of business in Woodcliff Lake, New Jersey, and is a citizen of New Jersey and Delaware. Par principally

develops, manufactures and markets generic versions of brand name drugs.

15. Defendant, Paddock, is a privately-held pharmaceutical company with its principal place of business in Minneapolis, Minnesota. Paddock principally develops, manufactures and markets generic versions of brand name drugs.

### **BACKGROUND**

#### **The Regulatory System Governing Pharmaceuticals In The United States**

##### **A. New Drug Applications**

16. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, (“FD&C Act”) as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”), and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, codified at 21 U.S.C. § 355(j) and 35 U.S.C. § 27 1(e) (2005), establishes procedures designed to facilitate competition from lower-priced generic drugs.

17. Approval by the FDA (the governmental body charged with regulating the pharmaceutical industry) is required before a company may begin selling a new drug in interstate commerce in the United States. 21 U.S.C. § 355(a). Pre-market approval for a new drug must be sought by filing a new drug application (“NDA”) with the FDA under § 355(b) of the FD&C Act demonstrating that the drug is safe and effective for its intended use.

18. New drugs that are approved for sale in the United States by the FDA are often covered by patents, which provide the patent owner with the ability to seek to exclude others from making, using, and/or selling (depending on the scope of the patent) that new drug in the United States for the duration of the patents, plus any extension of the original patent granted pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355.

19. Pursuant to 21 U.S.C. § 355(b), in its NDA the pioneer drug manufacturer must list those patents that claim the drug for which FDA approval is being sought or that claim a method of using the drug and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug. Once the NDA is approved by the FDA, any such patents are listed with the NDA in a publication known as the Approved Drug Products With Therapeutic Equivalence Evaluations, commonly referred to as the “Orange Book.”

20. Federal regulations impose strict limitations on the types of patents that a NDA holder can submit to the FDA for listing in the Orange Book. *See generally* 21 C.F.R. § 314.53. One such limitation is imposed by 21 C.F.R. § 314.53(b), which explicitly prohibits NDA holders from listing any patent in the Orange Book unless a claim of infringement could reasonably be asserted on the basis of such a patent.

21. Despite the FDA regulations that limit the types of patents that NDA holders can list in the Orange Book, it has become common for brand-name pharmaceutical companies to list in the Orange Book any and every patent they may be able to obtain, so as to force generic manufacturers to file what, as described below, is commonly known as a “Paragraph IV certification.”

22. The FDA does not police the listing of patents. The FDA employs no adjudicatory or other process to determine whether a patent submitted by a NDA holder qualifies for listing in the Orange Book and the FDA has stated that it lacks the resources and expertise to review the patents submitted in connection with NDAs.

23. As a result, the FDA’s role in the patent listing process is purely ministerial, and

it relies entirely upon the good faith of the NDA holder submitting the patent for listing.

## **B. Generic Drugs**

24. Generic drugs are drugs that the FDA has found to be bioequivalent to their corresponding brand name drugs. A generic drug provides identical therapeutic benefits and has the same side effects and safety profile as its corresponding brand-name drug.

25. Generic drugs invariably cost substantially less than the branded drugs to which they are bioequivalent. Typically, the first generic version of a brand-name drug is sold at a substantial discount to the brand, followed by increasingly steeper discounts as more generics of that molecule enter the market.

26. Under the Hatch-Waxman Act, a generic drug manufacturer may seek expedited FDA approval to market a generic version of a brand name drug with an approved NDA by filing an ANDA. An ANDA relies on the safety and efficacy data already filed with the FDA by the manufacturer of the equivalent brand name drug.

27. After an applicant has submitted its ANDA to the FDA it must file a patent certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii). Four types of certifications are available:

- a. The brand-name manufacturer has not filed patent information with the FDA (a “Paragraph I certification”);
- b. The patent or patents listed in the Orange Book have expired (a “Paragraph II certification”);
- c. The patent will expire on a date in the future, and the generic manufacturer does not seek to market its generic version of the drug prior to the date of expiration (a “Paragraph III certification”); or

d. The patent is invalid or not infringed by the generic manufacturer's product (a "Paragraph IV certification").

28. A generic drug applicant must serve the manufacturer of the brand-name drug with a copy of any certification under Paragraph IV. The Paragraph IV certification constitutes a "technical act of infringement" under Hatch Waxman which creates jurisdiction in the federal courts to entertain a patent infringement action and gives the NDA holder forty-five days from the date of the notice to institute such an action against the generic manufacturer under 35 U.S.C. § 271(e)(2). If such a suit is initiated, the FDA's approval of the ANDA is automatically stayed for up to thirty months. 21 U.S.C. § 355(j)(5)(B)(iii).

29. Because of this thirty-month stay, the mere filing of an infringement action in response to a Paragraph IV certification, regardless of the action's underlying merit, gives the brand-name company the functional equivalent of a self-effectuating preliminary injunction blocking the entry of a generic competitor, without ever having to establish, *inter alia*, likelihood of success on the merits, irreparable harm, that the balance of hardships is in its favor, or that the public good is served by the blocking of entry.

30. An improper Orange Book listing has additional anticompetitive effects, because the first generic company to file an ANDA with a Paragraph IV certification is, upon FDA approval, granted a 180-day period of marketing exclusivity in relation to other generic manufacturers. 21 U.S.C. § 355(j)(5)(B)(iv). This 180-day exclusivity period is awarded to the first Paragraph IV filer regardless of whether or not the brand company institutes pre-approval patent infringement litigation in response to the Paragraph IV certification. Absent an improper Orange Book listing, no Paragraph IV certification would be required and, thus, no generic

company would receive 180-day exclusivity; rather, multiple generic competitors would enter the market simultaneously.

31. Defendants were at all times fully familiar with their ability to delay the entry of generic competition by the improper manipulation of the patent listing and pre-approval litigation provisions of the Hatch-Waxman Act and related legislation.

### **The Consumer Benefits Of Generic Drugs**

32. Upon their introduction, generic drugs generally enter the market at prices 30% to 50% (or more) below the price of their brand-name equivalents. Because generic and branded drugs are fully interchangeable in terms of safety and efficacy, the vast majority of patients are switched to the less expensive generic in place of the brand-name drug.

33. Almost all states (and the District of Columbia) encourage generic competition through laws that allow pharmacists to substitute brand-name drugs with their “AB-rated” generic equivalents, unless a physician directs or the patient requests otherwise.

34. Many third-party payors of prescription drugs (*e.g.*, health insurance plans, Medicaid programs) have adopted policies to encourage the substitution of available AB-rated generic drugs for their branded counterparts.

### **DEFENDANTS’ ANTICOMPETITIVE CONDUCT**

35. The hormone testosterone, which is contained in Androgel, is unpatented. Patents which covered the synthesis of artificial testosterone expired many years ago.

36. Androgel is a brand name drug marketed by Unimed and used for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone. Androgel is indicated to treat those men with primary hypogonadism and

hypogonadotropic hypogonadism. Low testosterone levels are often associated with advancing age, certain diseases such as certain cancers, diabetes and HIV/AIDS.

37. Androgel is a topically applied gel formulation of testosterone which provides for a controlled release of testosterone into the bloodstream. Androgel's generic name is testosterone topical.

38. In August 1995, Unimed licensed the U.S. rights to the topical testosterone gel formulation used for Androgel from the Belgian pharmaceutical company Besins Healthcare, S.A. (together with its affiliates, "Besins"), which had developed the formulation. At that time, Besins agreed to provide commercial supply of Androgel to Unimed after FDA approval was granted.

39. Unimed filed with the FDA a NDA (No. 021015) for Androgel in April 1999. The NDA was approved in 2000, and Unimed began selling Androgel soon thereafter.

40. Unimed listed the 894 patent in the FDA's Orange Book, claiming that the patent was valid and its claims covered the formulation of Androgel. The formulation patent expires in August 2020.

41. In or about May 2003, Watson and Paddock each filed an ANDA with the FDA seeking approval to market a generic version of Androgel. Both applications contained a Paragraph IV certification claiming that the 894 patent was invalid, unenforceable, and/or not infringed by its ANDA.

42. Watson, which filed its ANDA before Paddock, was awarded 180-day exclusivity under the Hatch-Waxman Act. In or about January 2006, Watson received final approval from the FDA to market its generic version of testosterone topical.

43. In or about July 2003, Paddock and Par entered into an agreement whereby Par would sell the generic version of Androgel in the United States that Paddock manufactured.

44. On October 27, 2004 Paddock's ANDA was tentatively approved.

45. In September 2006, Par announced that it purchased all of Paddock's rights to Paddock's ANDA for generic Androgel.

46. In August, 2003, Unimed filed patent infringement lawsuits against Watson and Paddock, claiming that each infringed the 894 patent. No dispositive motions were filed in the underlying patent litigation until late 2005. Under the Hatch-Waxman Act, Unimed's patent infringement lawsuits triggered automatic stays of FDA final approval of the generic versions of Androgel until January 2006.

47. Because Unimed knew that there would be a stay in effect until January 2006, Unimed had little, if any, incentive to do anything prior to January, 2006.

48. As alleged above, in January 2006, Watson received final FDA approval for its generic version of Androgel which meant that the FDA determined that Watson's generic was as safe and effective as branded Androgel. This approval would allow Watson to launch its generic version of Androgel unless Unimed could obtain a preliminary injunction in the patent infringement case to stop the launch.

49. Unimed did not file for a preliminary injunction to prevent Watson from launching a generic version of Androgel, but rather formulated anticompetitive agreements to settle the patent disputes and eliminate the threat of competition by a generic.

50. Unimed agreed to pay Watson an undisclosed amount for its agreement to delay its launch of generic Androgel. Watson had a 180-day exclusivity period which meant that by

delaying its own launch, Watson could also delay the later generics from entering the market.

51. Unimed also agreed to pay \$60 million to Paddock and Par (who were in less advantageous positions than was Watson) for their agreement to delay their market entry of their AB rated generic Androgel.

52. In addition, all of the Defendants jointly agreed to horizontally allocate the market for testosterone topical. Defendants' pretextual reasons for the payments were for, *inter alia*, co-promotion and back-up manufacturing. However, these rationalizations were meant to conceal the fact that the payments were a mechanism by which Unimed could pass on to the Generic Defendants some of Unimed's supracompetitive's profits earned during the period of delay. The co-promotion and back-up manufacturing were of little value to Unimed, and most certainly, worth substantially less than the tens or hundreds of millions of dollars Unimed paid to the Generic Defendants.

53. The anticompetitive agreements between the Defendants have not been examined nor approved by any governmental antitrust authority. In fact, since news of the agreements became public, the Federal Trade Commission (and potentially other governmental authorities) has been investigating Defendants' anticompetitive conduct concerning Androgel. *See FTC v. Tarriff*, No. 08-217 (RLC), 2008 U.S. Dist. LEXIS 42739, at\*2 (D.D.C. June 2, 2008) (noting the FTC's investigation "to determine whether agreements between [Unimed] and Par and Paddock, or any other agreement, unlawfully delayed entry of a lower-cost generic version of the drug AndroGel"). On February 12, 2009, the FTC filed an amended complaint in its action against these defendants, in which it sets forth in detail the anti-competitive conduct of defendants. *See FTC v. Watson Pharm, Inc., et al.*, No. 2:09-cv-598-MRP-PLA (C.D. Cal.) (D.I.

8).

54. Defendants are well aware that any delay in generic entry leads directly to damages to Plaintiff and the Class it seeks to represent as well as continuing inflated profits because it allows them to continue to enjoy the benefits of an absence of competition for Androgel. In the meantime, any such delay causes substantial harm to indirect purchasers of Androgel.

55. Absent Defendants' Agreement, Watson would have begun marketing its generic Androgel after it received FDA approval of its ANDA on or about January 2006.

56. If a generic version of Androgel had been introduced to the market, Plaintiff and members of the Class would have substituted the lower-priced generic Androgel for all or a portion of their purchases of branded Androgel, or would have paid substantially less for branded Androgel because Unimed would have lowered net Androgel prices in response to competition, or would have reduced the rate of price increases for Androgel in response to such competition.

57. As a consequence of Defendants' Agreement, Plaintiff and members of the Class have been deprived of the benefits of free and open competition in their purchases. Purchasers of Androgel were required to continue purchasing brand name Androgel when a less expensive generic product would have otherwise been available

#### **CLASS ACTION ALLEGATIONS**

58. Plaintiff brings this action pursuant to Rule 23(b)(2) and (b)(3) of the Federal Rules of Civil Procedure, on behalf of itself and the following Class (the "Class"):

All persons and entities throughout the State of Florida who purchased Androgel by themselves, their families, or their members, employees,

insureds, participants, or beneficiaries (the “Class”) during the period from at least January 2006, through the date on which the anticompetitive effects of Defendants’ conduct cease (“Class Period”). Excluded from the Class are all Defendants, their officers, subsidiaries and all affiliates; all government entities (except for governmental-funded employee benefit plans); and all persons or entities that purchased Androgel for purposes of resale, or directly from any of the Defendants or affiliates.

59. The Class is so numerous that joinder of all members is impracticable. Upon information and belief, the Class includes hundreds, if not thousands, of members. The precise identity of the Class members can be ascertained from the records of Defendants.

60. There are questions of law and fact common to the Class, including but not limited to, the following:

- a. whether Defendants combined, agreed, or conspired as alleged herein in restraint of trade;
- b. whether Defendants’ agreement, combination, or conspiracy was lawful;
- c. whether Defendants’ unlawful conduct as alleged herein has affected interstate commerce;
- d. whether Defendants’ unlawful conduct caused Plaintiff and the other members of the Class to pay more for Androgel and its generic equivalents than they would have paid absent Defendants’ conduct; and
- e. whether Defendants’ unlawful conduct caused antitrust injury to the business or property of Plaintiff and the members of the Class and, if so, the appropriate relief and/or measure of damages.

61. These and other questions of law and fact are common to the members of the Class and predominate over any questions affecting individual members because Defendants

have acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendants' collusive conduct.

62. Plaintiff's claims are typical of the claims of the Class because Plaintiff and all Class members suffered antitrust injury by the same wrongful conduct by the Defendants. All Class members have all paid artificially inflated prices for Androgel and its generic equivalents resulting from Defendants' Agreement to exclude generic competition.

63. Plaintiff will fairly and adequately represent and protect the interests of the Class. Plaintiff has retained counsel experienced in class action and antitrust litigation. Plaintiff has no interest in this litigation that is adverse to, or in conflict with, the interests of the other members of the Class.

64. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would require. The benefits of proceeding by way of class action, including providing injured persons or entities with a method for obtaining redress on claims that they might not be able to pursue individually, substantially outweigh any difficulties that may arise in the management of a class action.

65. Plaintiff knows of no difficulty that would be encountered in the management of the claims advanced by the Class that would preclude certification.

#### INTERSTATE TRADE AND COMMERCE

66. During the period relevant to this litigation, Androgel was sold throughout the

United States. Androgel was manufactured and sold in a continuous and uninterrupted flow of commerce across state lines. In connection with the sale and purchase of Androgel, monies, contracts, bills, terms and other business communications were transmitted in interstate commerce. Defendants' unlawful activities alleged in this Complaint have occurred in and have had a substantial effect upon interstate commerce.

67. In furtherance of their unlawful conduct, Defendants employed the United States mail and interstate and international telephone lines, as well as means of interstate and international travel. The activities of Defendants, as alleged herein, were within the flow of, and have substantially affected, interstate commerce.

#### **ANTICOMPETITIVE EFFECTS**

68. Defendants have undertaken the foregoing unlawful courses of conduct for the following purposes and with the following effects:

- a. prices for Androgel and its generic equivalents have been fixed, raised, maintained, or stabilized at artificially high and non-competitive levels;
- b. buyers of Androgel have been unable to purchase lower-priced generic versions of Androgel;
- c. buyers of Androgel and its generic equivalents have been deprived of the benefits of free and open competition in their purchases; and
- d. competition in the production and sale of Androgel and its generic equivalents has been restrained, suppressed, and eliminated.

#### **DAMAGES**

69. During the relevant period, Plaintiff and members of the Class purchased

substantial amounts of Androgel. As a result of Defendants' illegal conduct, Plaintiff and members of the Class were compelled to pay, and did pay, artificially inflated prices for Androgel. Those prices were and are substantially greater than the prices they would have paid absent the illegal agreement, combination, conspiracy, and other unlawful conduct alleged herein, because they were deprived of the opportunity to: (1) pay lower prices for the generic versions of the drug; (2) pay lower prices for their Androgel requirements by switching more of the volume of their purchases from the brand to the generic versions; and (3) pay lower prices for the brand name drug Androgel. Members of the Class have sustained substantial losses and damage to their businesses and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

### **COUNT I**

#### **(FOR DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR VIOLATIONS OF SECTION 1 OF THE SHERMAN ACT)**

70. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

71. By entering into the Agreement, the purpose and effect of which was to restrain trade by keeping generic competition to Androgel out of the market, Defendants have engaged in a continuing contract, conspiracy in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

72. Defendants' contract, combination, and/or conspiracy has included concerted actions and undertakings among Defendants with the purpose and effect of fixing, raising, maintaining, or stabilizing the price of Androgel and its generic equivalents.

73. For the purpose of formulating and effectuating their contract, combination, and/or conspiracy, Defendants performed, among others, the following acts:

a. entering into illegal agreements by which the Generic Defendants agreed not to sell generic Androgel in U.S. commerce in exchange for the promise of monetary payment by Unimed; and

b. depriving indirect purchasers of the ability to purchase Androgel and its generic equivalents at a competitive price.

74. The acts done by each of the Defendants as part of, and in furtherance of, their contract, combination, and/or conspiracy were authorized, ordered, or done by their officers, agents, employees, or representatives while actively engaged in the management of Defendants' affairs.

75. Defendants' illegal contract, combination, and/or conspiracy to prevent the introduction into the U.S. marketplace of a generic version of Androgel resulted in Plaintiff and members of the Class paying more than they would have paid for Androgel and its generic equivalents absent Defendants' illegal conduct.

76. The purpose and effect of Defendants' conduct was to unreasonably restrain competition in the sale of Androgel and its generic equivalents. To the extent required by law, the relevant product market is Androgel and its AB-rated generic equivalents, and the relevant geographical market is the State of Florida.

## COUNT II

### **FOR DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT**

77. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

78. By engaging in willful and exclusionary acts as part of a scheme to maintain and extend their monopoly power over Androgel, Unimed has violated Section 2 of the Sherman Act, U.S.C. § 2.

79. By instituting litigation against Generic Defendants based on the blatantly unenforceable and invalid 894 Patent, Unimed engaged in sham litigation, which constitutes a willful and exclusionary act as part of a scheme to maintain and extend their monopoly power over Androgel.

80. Unimed's actions to prevent the introduction into the U.S. marketplace of a generic version of Androgel resulted in Plaintiff and members of the Class paying more than they would have paid for Androgel and its generic equivalents absent Unimed's conduct.

81. To the extent required by law, the relevant product market is Androgel and its AB-rated generic equivalents. There are no reasonable economic substitutes for Androgel other than the AB-rated generic equivalents. Accordingly, Unimed has been able to profitably maintain the price of Androgel well above competitive levels.

82. The relevant geographic market is the State of Florida.

### **COUNT III**

#### **VIOLATION OF FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT (FLORIDA STAT. ANN. § 501.201 *et seq.*)**

83. Plaintiff realleges and incorporates herein by reference all of the preceding paragraphs.

84. The conduct described above constitutes unfair or deceptive practices predominantly affecting the conduct of trade or commerce in violation of Fla. Stat. Ann.

§501.201, *et seq.*, particularly Fla. Stat. Ann. §501.204.

85. By reason of the violations of Fla. Stat. Ann. §501.201, *et seq.*, Plaintiff and other members of the Proposed Class have been injured in that they have paid more for Androgel than they would have in the absence of the Defendants' unfair or deceptive practices.

86. Pursuant to Fla. Stat. Ann. §501.201, *et seq.*, particularly §501.211, Plaintiff demands damages, as well as restitution from Defendants of all overcharges paid by Plaintiff and Proposed Class members. Further, Plaintiff and the Proposed Class demand all further necessary and proper relief to which they are justly entitled.

#### COUNT IV

##### **(FOR RESTITUTION, DISGORGEMENT AND CONSTRUCTIVE TRUST FOR UNJUST ENRICHMENT BY DEFENDANTS)**

87. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

88. As a result of their unlawful conduct described above, Defendants have been and will continue to be unjustly enriched. Defendants' unlawful acts impose barriers to entry for generic manufacturers seeking to compete in the relevant market. Defendants have been unjustly enriched, to the detriment of Plaintiff and the Class by the receipt of, at a minimum, unlawfully inflated prices and illegal profits on their sale of Androgel products. Defendants have benefitted from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of their ill-gotten gains resulting from the overpayments for Androgel products made by Plaintiff and the Class.

89. Plaintiff and members of the Class are entitled to the amount of Defendants' ill-gotten gains resulting from Defendants' unlawful, unjust and inequitable conduct. Plaintiff

and the Class are entitled to the establishment of a constructive trust consisting of all ill-gotten gains from which Plaintiff and the Class members may make claims on a pro rata basis.

**JURY DEMAND**

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of all issues so triable.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff, on behalf of itself and members of the Class, respectfully requests:

1. An order certifying this action as a class action and appointing Plaintiff as representative of the Class and its counsel as Class Counsel;
2. A judgment declaring Defendants' contract, combination, or conspiracy and monopolization and conspiracy to monopolization as alleged herein to be an unlawful restraint of trade in violation of Sections 1 and 2 of the Sherman Act, in violation of the antitrust and consumer protection statutes set forth above, and common law of unjust enrichment;
3. A judgment for Plaintiff and the Class and against Defendants for damages and, where applicable, treble, multiple, and other damages, including interest on the damages sustained by Plaintiff and the other members of the Class;
4. Plaintiff and each member of the Class recover the amounts by which Defendants have been unjustly enriched;
5. Joint and several judgment be entered against each Defendant in favor of Plaintiff and the other members of the Class;
6. An award to Plaintiff of all costs incurred, including reasonable attorneys' fees; Pre- and post-judgment interest; and

7. Such other and further relief as the Court deems just and proper.

Dated: April 17, 2009

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